

**REMARKS**

Claims 1-28 are currently pending in this application; claims 30-48 have been withdrawn. Claims 1 and 23 have been amended. Upon entry of these amendments, claims 1-28 will be pending and under active consideration. Claims 1 and 23 are independent.

Applicants submit respectfully that the amendments presented herein are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter. Claims 1 and 23 have been amended herein to recite “in which at least one compartment is charged with a gaseous nutrient substantially free of non-gaseous fluids.” The amendments are supported fully by the claims, figures, and throughout the specification as originally filed. These amendments find support, at least, in any of the Examples 6.1-6.8.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. Claim Rejections Under 35 U.S.C. § 103**

**A. The rejections over Robinson**

Claims 1-14, 18-21 and 23-27 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,015,585 to Robinson *et al.* (hereinafter, “Robinson”). Essentially, the Examiner has alleged that “it would have been obvious...to add a second bioreactor unit to the previously disclosed apparatus since it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art.” (Citation omitted.) With regard to the Applicants’ assertion that the Robinson device does not provide for any compartment that may be *dedicated* to gaseous, integral aeration, the Office Action states that the argument is narrower than the device claimed. The Examiner appears to concede that Robinson specifically discloses oxygen transport in his device, though it is combined with a fluid for easy transport. Nonetheless, “Applicants have failed to claim that the oxygen transport in the instant device is oxygen that is free of other nutrients or not in solution.” Applicants traverse respectfully.

Without acquiescing to the propriety of the rejection, Applicants have amended independent claims 1 and 23 to recite, in relevant part, a bioreactor “in which at least one compartment is charged with a gaseous nutrient substantially free of non-gaseous fluids.”

Applicants respectfully submit that each of the elements of the claims, as amended, are not present in the prior art and therefore, the references cited, alone or in combination, cannot be properly used to arrive at the instant invention.

Accordingly, Applicants respectfully submit that the rejection of Claims 1-14, 18-21 and 23-27 under 35 U.S.C. § 103(a) have been overcome, and request respectfully that the rejection of the pending claims under 35 U.S.C. § 103(a) be withdrawn.

**B. The rejections over Robinson in view of Naughton**

Claims 15, 22 and 28 stand rejected under 35 U.S.C. § 103(a) over Robinson in view of U.S. Patent No. 6,218,182 to Naughton *et al.* (hereinafter, “Naughton”). The Office Action states that Robinson does not disclose treatment of a patient, but alleges that this deficiency in Robinson is cured by Naughton. Applicants traverse respectfully.

Applicants respectfully submit that the novel devices and methods of the present invention are neither taught nor suggested by Robinson, either alone or in view of Naughton. There is neither teaching nor suggestion in these references that the device include integral aeration means, such as the integral gas inlets and outlets for a fourth compartment as claimed in the present invention. Indeed, neither of the references teaches “a bioreactor... in which a compartment is charged with a gaseous nutrient substantially free of non-gaseous fluids,” as claimed. Thus, Applicants submit respectfully that, as Naughton fails to cure the deficiencies of Robinson with respect to a compartment charged with a gaseous nutrient substantially free of non-gaseous fluids, the combination of Robinson with Naughton similarly fails to meet the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicants respectfully submit that the rejection of claims 15, 22 and 28 under 35 U.S.C. § 103(a) have been overcome, and Applicants request respectfully that the rejection of claims 15, 22 and 28 under 35 U.S.C. § 103(a) be withdrawn.

**C. The rejection over Robinson in view of Naughton in view of Stephanopoulos**

Claims 16 and 17 remain rejected over Robinson in view of Naughton and further in view of U.S. Patent No. 5,510,262 to Stephanopoulos *et al.* (hereinafter, “Stephanopoulos”) under 35

U.S.C. § 103(a). Briefly, the Office Action states that Robinson and Naughton teach Applicants' claimed device with the exception of aeration and perfluorocarbon coating on the microfiber growth area and that Stephanopoulos cures this deficiency. Applicants traverse respectfully.

While admitting that Robinson in view of Naughton is deficient with respect to Applicants' claimed invention, the Office Action alleges that Stephanopoulos cures those deficiencies by teaching a hollow fiber cell culture device, wherein the medium is aerated by containment in a growth medium reservoir and that perfluorocarbon may be added to the medium to increase the oxygen solubility in the growth medium. Applicants submit respectfully that Stephanopoulos in combination with Robinson and Naughton does not teach Applicants' claimed invention. Robinson, as noted above, at best teaches away from the claimed invention.

Even assuming, *arguendo*, that Stephanopoulos could be combined with Robinson in view of Naughton, such a combination would not cure Robinson's deficiencies. As stated in the Office Action, Stephanopoulos teaches a hollow fiber cell culture device wherein the medium is aerated by containment in a growth medium reservoir, from which the nutrient medium is circulated into the bioreactor, and that perfluorocarbon may be added to the medium to increase the oxygen solubility in the growth medium. As Applicants have asserted, their invention is based on the presence of a compartment dedicated to a gaseous nutrient – substantially free of non-gaseous fluids. No amount of manipulation of the disclosures of the cited references discloses, teaches, or suggests this feature. Thus, Applicants submit respectfully that the proposed combination of Robinson, Naughton and Stephanopoulos is improper and in any event does not account for all the elements of the invention as claimed.

Accordingly, Applicants submit respectfully that the rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) has been overcome, and Applicants request respectfully that the rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) be withdrawn.

### **CONCLUSION**

Applicants submit respectfully that the present application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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